

CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application.

1. (Currently Amended) A composition comprising ibuprofen and diphenhydramine in amounts effective to treat a pain-associated sleep disturbance, wherein the composition is a bilayer tablet or a bilayer caplet formulated to prevent negative interactions between the diphenhydramine and the ibuprofen by separating the ibuprofen and the diphenhydramine into different layers.
- 2-5. (Canceled)
6. (Previously Presented) A composition comprising ibuprofen and diphenhydramine in amounts effective to treat a pain-associated sleep disturbance formulated in a soft gelatin capsule containing polyethylene glycol to prevent negative interactions between the ibuprofen and the diphenhydramine.
7. (Previously Presented) The composition of any one of claims 1 or 6, wherein the ibuprofen is present in an amount from 50 mg to 800 mg.
8. (Currently amended) The composition of any one of claims 1 or 6, wherein the ibuprofen is presented present in an amount of 200 mg.
9. (Previously Presented) The composition of any one of claims 1 or 6, wherein the diphenhydramine is present as diphenhydramine HCl or diphenhydramine citrate.
10. (Original) The composition of claim 9, wherein the diphenhydramine HCl is present in an amount from 12.5 mg to 50 mg.

11. (Original) The composition of claim 9, wherein the diphenhydramine HCl is present in an amount of 25 mg.
12. (Original) The composition of claim 9, wherein the diphenhydramine citrate is present in amount from 19 mg to 38 mg.
13. (Original) The composition of claim 9, wherein the diphenhydramine citrate is present in an amount of 38 mg.
- 14-25. (Canceled)
26. (New) The composition of any one of claims 1 or 6, wherein the sleep disturbance affects sleep duration.
27. (New) A composition comprising ibuprofen and diphenhydramine in amounts effective to treat a pain-associated sleep disturbance, wherein:
 - a) the composition is a bilayer tablet or a bilayer caplet formulated to prevent negative interactions between the diphenhydramine and the ibuprofen by separating the ibuprofen and the diphenhydramine into different layers; and
 - b) the composition is effective to treat a pain-associated sleep disturbance within 60 minutes.
28. (New) A composition comprising ibuprofen and diphenhydramine in amounts effective to treat a pain-associated sleep disturbance, wherein:
 - a) the composition is a bilayer tablet or a bilayer caplet formulated to prevent negative interactions between the diphenhydramine and the ibuprofen by separating the ibuprofen and the diphenhydramine into different layers; and
 - b) the ibuprofen is a free acid.

29. (New) A composition comprising ibuprofen and diphenhydramine in amounts effective to treat a pain-associated sleep disturbance, wherein:

- a) the composition is a bilayer tablet or a bilayer caplet formulated to prevent negative interactions between the diphenhydramine and the ibuprofen by separating the ibuprofen and the diphenhydramine into different layers;
- b) the composition is effective to treat a pain-associated sleep disturbance within 60 minutes; and
- c) the ibuprofen is a free acid.

30. (New) A composition comprising ibuprofen and diphenhydramine in amounts effective to treat a pain-associated sleep disturbance, wherein:

- a) the composition is a bilayer tablet or a bilayer caplet formulated to prevent negative interactions between the diphenhydramine and the ibuprofen by separating the ibuprofen and the diphenhydramine into different layers; and
- b) the composition further comprises at least one of calcium stearate, croscarmellose sodium, glyceryl behenate, lactose, microcrystalline cellulose, silicon dioxide colloidal, sodium lauryl sulfate, sodium starch glycolate, corn starch, pregelatinized starch, starch or stearic acid.